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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,435	03/05/2001	Stephen R. Quake	3153/1G765US1	2542
7278	7590	02/17/2004	EXAMINER	
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			MAHATAN, CHANNING	
			ART UNIT	PAPER NUMBER

1631

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/800,435

Applicant(s)

QUAKE ET AL.

Examiner

Channing S Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-105 is/are pending in the application.
- 4a) Of the above claim(s) 48-105 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-47 is/are rejected.
- 7) ☒ Claim(s) 37 is/are objected to.
- 8) ☒ Claim(s) 1-105 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2 Sheets</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

APPLICANTS' ELECTION

Applicant's election with traverse of Group I (claims 1-47; directed to methods for analyzing hybridization data from a array) in the response filed 14 October 2003 is acknowledged. The traversal is on the ground(s) that there is no burden of search, wherein Applicants assert Groups I-III do not define methods or compositions which are sufficiently distinct to warrant separate examination and searches. This is not found persuasive because the 'Election/Restriction' requirement, mailed 15 September 2003, indicated each of the groups would require differing searches in substantially non-overlapping areas based on the differing method steps, different data and information utilized, and different goals achieved in each of the groups. Thus, a burden of search has been established. The requirement is still deemed proper and is therefore made FINAL.

Claims 48-105 are withdrawn from further consideration pursuant to 37 C.F.R. § 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the response filed 14 October 2003.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-47.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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LACK OF ENABLEMENT

Claims 1-47 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q. 2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Claims 1-47 are rejected under 35 U.S.C. § 112, first paragraph. The claimed invention is directed to a “method for analyzing data from hybridization of a sample to an array of oligonucleotide probes”. The instant claims recite only “a step of separately analyzing the data for the oligonucleotide probes in each subblock” and fails to provide further steps/procedures of analysis.

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The specification discloses the invention relates to the identification of the expression pattern of each gene in an organism of interest from a microarray (Abstract, and page 2).

Example 1 describes the theoretical correlation between the optical signals generated during hybridization experiments to gene expression levels in the mouse and yeast genome through the calculation of vectors of hybridization signals and the matrix of binding affinities. The dimensionality of the matrix of binding affinities is reduced by inversion through the disclosed algorithm (Example 2 entitled 'Algorithm for determination of gene expression patterns). The gene expression levels are then solved by carrying out the matrix multiplication in Equation (3).

However, the specification fails to disclose the step of "analyzing the data for the oligonucleotide probes in each subblock". In the absence of any further steps/procedures one skilled in the art would not understand: 1) what analysis procedures are to be performed?; and 2) what data the oligonucleotide probes in each subblock is analyzed (refer to below 35 U.S.C. 112 2nd Paragraph Rejection). Additionally, the specification is devoid of any intent or goal that would be achieved through the implementation of the instantly claimed method by "analyzing the data for the oligonucleotide probes in each subblock". For instance, after the data for the oligonucleotide probes in each subblock is analyzed: 1) what does the information represent/mean?; and 2) what does one do with this information? No guidance, direction, or examples are provided such that one of ordinary skill in the art would have known how to use the claimed invention (i.e. step of "analyzing the data for the oligonucleotide probes in each subblock).

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-47 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claim 1 and all claims dependent therefrom are confusing wherein the “sample” and “oligonucleotide probes” limitations found in the preamble are not within the body of the claim. Lines 1-8 of claim 1 is viewed as language regarding the preamble and only lines 9-10 are viewed as the body. If it is Applicants’ intent that such limitations are to be part of the body of the claim clarification, via clearer claim language, is requested.

Claim 1 and all claim dependent therefrom are indefinite due to the lack of clarity of the claim language failing to recite positive/active process step(s), which agrees with the preamble. The preamble states that it is “A method for analyzing data from hybridization of a sample to an array of oligonucleotide probes”, however, the claim(s) fail to recite steps of performing the “method for analyzing data” and it is unclear what steps are to be performed. It is acknowledged instant claim 1 states the “method comprises a step of separately analyzing the data for the oligonucleotide probes in each subblock”, however, as written no steps for “analyzing the data for the oligonucleotide in each subblock” is recited. The language “analyzing the data” is not considered to be a positive, active step with a known or well-understood meaning in the art. The dependent claims do not provide any steps for “analyzing the data for the oligonucleotide probes

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in each subblock”. While minor details are not required in method/process claims, at least the basic step must be recited in a positive/active fashion. The claim(s) do not set forth conditions/steps of the instant claimed method and it is unclear what is to be performed. Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 2-47 are confusing, wherein said claims provide limitations directed only to the preamble of claim 1, and fail to further limit the method step of claim 1. It is unclear if it is Applicants’ intent that such limitations are to be part of the body of the instantly claimed method. Clarification, via clearer claim language, is requested.

Claims 7, 8, 9, 19, 20, 21, and all claims dependent therefrom recites the term(s) “associating”/“associated” which is vague and indefinite. It is unclear as to the limitations Applicants refers to as “associating”/“associated”, wherein such terminology implies some of criteria for “associating”. For example, claim 7 states “associating a gene g_a with a gene list for a subblock, wherein the gene g_a is not already associated with a gene list for a subblock”; it is unclear the criteria(s) which establish gene g_a to be associated or not already associated with gene list for a subblock. Applicants can resolve this issue by particularly pointing out the criteria(s) that establish “associating”/“associated”. Clarification of the metes and bounds, via clearer claim language, is requested.

OBJECTION TO CLAIMS

Claim 37 is objected to because of a spelling error wherein “controled” should be corrected to “controlled”.

OBJECTION TO DISCLOSURE

The disclosure is objected to because of the following informalities:

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The specification is objected to because of the following spelling errors:

page 29 (line 15) wherein “controled” should be corrected to “controlled”; and

page 42 (line 23) wherein “exdample” should be corrected to “example”.

The specification contains embedded hyperlinks and/or other form of browser-executable code on pages 38 (lines 20-21) and page 39 (lines 5-6), which are impermissible in the text of the application as they represent an improper incorporation by reference. See M.P.E.P. § 608.01 and 608.01(p). Applicant is requested to review the application for embedded hyperlinks and/or other forms of browser-executable code and delete them. A suggested format for reference to internet websites/addresses is: “URL address: genome-www.Stanford.edu/Saccharomyces/”.

INFORMATION DISCLOSURE STATEMENT

The ‘Information Disclosure Statement’ filed 23 August 2001 indicates it consists of three(3) sheets, however, only ‘Sheet 1 of 3’ was located and therefore considered. Should Applicants desire consideration of Sheets 2 and 3 it is requested Applicants provide a new ‘Information Disclosure Statement’ and copies of the references.

Appropriate Correction Is Requested.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and

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1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (571) 272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *February 9, 2004*
Examiner Initials: *CSM*

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
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